

d.) **Remarks**

In the Office Action, restriction is deemed required, under 35 U.S.C. §121, to one of the following groups of claims:

**Group I:** Claims 1-15, drawn to monoclonal antibodies specifically reactive against B. anthracis (class 530, subclass 388.1);

**Group II:** Claims 16-20, drawn to a kit comprising an antibody, which is specifically reactive against spores or vegetative cells of B. anthracis, B. thuringiensis, and B. cereus (class 435, subclass 975);

**Group III:** Claims 21-32, drawn to a method for producing a species-specific antibody of one species of Bacillus (class 424, subclass 130.1);

**Group IV:** Claim 35, drawn to an antibody that is specifically reactive to B. thuringiensis and not B. anthracis or B. cereus (class 530, subclass 387.1);

**Group V:** Claim 36, drawn to an antibody that is specifically reactive to B. cereus and not B. thuringiensis or B. anthracis (class 530, subclass 387.1);

**Group VI:** Claims 37, 38, 40 and 41, drawn to an isolated or recombinant antigen comprising an EA1 protein of the surface layer of B. anthracis (class 530, subclass 350);

**Group VII:** Claim 39, drawn to a method of detecting B. anthracis by using the EA1 protein (class 435, subclass 7.4); and

**Group VIII:** Claims 42 and 43, drawn to a therapeutic agent comprising antibodies to the EA1 protein and methods for treating, preventing and controlling B. anthracis infection (class 424, subclass 164.1).

As recited under M.P.E.P. 803, restriction is appropriate only when the groups can be shown to be distinct and there would be a "**serious burden**" placed on the Examiner to examine more than one group of claims. No such serious burden has been established and applicant respectfully requests that this restriction be withdrawn.

First, in the instant application, all of the claims are directed to tools and methods for the immunological detection of anthrax. As such, a search of all claims would amount to a search of the same subject area and, thus, it should not be considered a serious burden on the examiner to

examine all of the claims together. It is respectfully requested that this requirement be withdrawn. Applicant further offers the following remarks.

First, and as stated above, there are two basic criteria for applying a restriction requirement. The invention must fall into one or more of the standards set forth in the Manual of Patent Examining Procedure ("MPEP"), and there must be a serious burden placed on the examiner to examine all claims together. The comments in Paper No. 9 with respect to the restriction relate only to the first criteria, application of the rules of the MPEP to this case. No comments are made with respect to the second criteria, why it would be a serious search burden. The burden to show the appropriateness of this restriction rests with the U.S. Patent and Trademark Office ("PTO"). As that burden has not been met, applicant respectfully requests that this restriction requirement be withdrawn.

Second, in reviewing the classification structure imposed, it appears that the groups fall into mostly the same or very closely related search groups. For example, most claim groups (Groups I, IV, and VI) fall into one class, namely, class 530. The remaining groups fall into closely related classes 424 and 435. Thus, examination of only these three classes would cover all of the claims. Further, two of these same groups (Groups IV and V) fall into the very same subclass, 387.1. Group I claims are in the nearly identical search class, 388.1, and Group II (subclass 975) and Group III (subclass 130.1) claims are also very similar. In view of the search structure alone, it is clear that examination of all claim groups would not impose a serious examination burden.

Lastly, in reviewing the subject matter of the claim groups, it is apparent that the searching burden has been targeted to "negative" criteria. For example, as stated in Paper No. 9:

"Groups I and II comprise different antibodies because the antibodies of Group I are reactive against *B. anthracis*, but not *B. cereus* or *B. thuringiensis*. The antibodies of Group II can be reactive against *B. cereus* and/or *B. thuringiensis*." (see page 3, last paragraph continuing to page 4).

"Further, the antibodies of Group I are different from those of Group III because they have specificity to *B. anthracis* while being non-reactive to *B. cereus* or *B. thuringiensis*." (see page 4, second

paragraph).

“The antibodies of Groups I, IV and V are structurally different and possess different specificities.” (see page 4, third paragraph).

Applicant respectfully asserts that by establishing negative limitations in the claim grouping, i.e., that an antibody is identified by its binding to one entity and its failure to bind to another entity), a proper search necessarily requires a knowledge of both positive and negative binding characteristics. Therefore, a search of any one group of specifically reactive antibodies (i.e. antibodies that bind to one species of *Bacillus* and not another) necessarily requires a search of the other group of specifically reactive antibodies. Take into consideration that a search of the Group II claims (kits containing specifically reactive antibodies) necessarily includes a search of the claims of Groups I (specifically reactive antibodies), IV (specifically reactive antibodies), V (specifically reactive antibodies), and also a search of the claims of Groups III (specifically reactive antibody production) and VII (detection by specific reactivity to an antigen). For at least this reason, applicant respectfully requests that the restriction be withdrawn at least with respect to Groups I-V and VII, and that all these claims be examined together.

As stated above, a restriction requirement is imposed "only" when it would be a serious burden on the examiner to examine all of the claims at once. As a serious burden is not imposed by an examination of all claims, withdrawal of the restriction and examination of all claim groups is respectfully requested. Alternatively, if a complete withdrawal is not granted, applicant respectfully requests that the restriction be re-evaluated and that Groups I-V and VII be combined and examiner together.

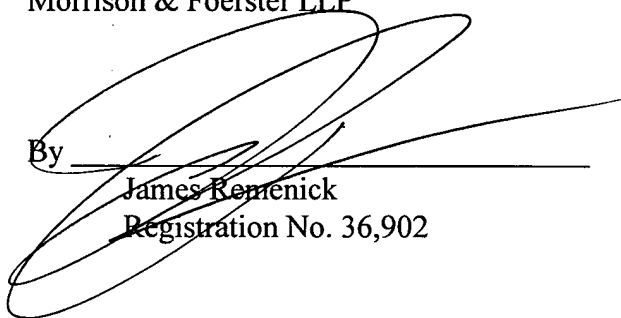
**Conclusion**

The application is in condition for examination and the prompt issuance of an Office Action is respectfully requested. If there are any additional fees due with the filing of this Response, including any additional fees for a further extension of time, not herein accounted for, applicant respectfully requests that extension and also requests that any and all fees due be charged to Deposit Account No. 03-1952.

Respectfully submitted,  
Morrison & Foerster LLP

Date: May 29, 2003

By

  
James Remenick  
Registration No. 36,902

Morrison & Foerster, LLP  
1650 Tyson's Blvd., Suite 300  
McLean, VA 22102  
(703) 760-7100 (telephone)  
(703) 760-7777 (telecopier)